TSUMURA & CO.

12-7, Nibancho, Chiyoda-ku, Tokyo 102-8422, Japan

Telephone: 03 3221 0155 Facsimile: 03 3221 0016

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May 19, 1999

Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition Food and Drug Administration 200 C St., S.W. Washington, DC 20204 U.S.A.

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16/3/59 18/3/59

Dear Sirs.

Notification of Statement on Dietary Supplement

In accordance with the Code of Federal Regulation revised as of April 1, 1998 §101.93 (a), I, Masaki Aburada, Ph.D. General Manager of International Division of Tsumura & Co., a Japanese corporation, do hereby notify:

(i) The name and address of the manufacturer of the dietary supplement that bears the statement.

Company name:

Tsumura & Co.

Registered address:

4-10, Nihombashi 3-chome, Chuo-ku, Tokyo 103-0027 Japan.

Head office address:

12-7, Nibancho, Chiyoda-ku, Tokyo 102-8422, Japan.

(ii) The text of the statement that is being made.

Helps regulate normal urinary excretion.

(iii) The name of the dietary ingredients that are subject of the statement.

Dried water extract of the following blend of raw herbs;

Rehmannia Root, Asiatic Dogwood Fruit, Chinese Yam Rhizome, Alisma Rhizome,

Poria Sclerotium, Tree Peony Bark, Cinnamon Bark and Prepared Aconite Tuber.

(iv) The name of the dietary supplement including brand name.

Herbal Supplement

HACHIMI-ЛО-GAN

IN WITNESS WHEREOF, I have hereunto set my hand on this 19th day of May, 1999.

Yours faithfully,

Tsumura & Co.

Masaki Aburada, Ph.D.

General Manager of International Division

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